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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,755	06/04/2007	Lamensdorf Itschak	P-6629-US	2243

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EXAMINER	
ZARA, JANE J	

ART UNIT	PAPER NUMBER
1635	

MAIL DATE	DELIVERY MODE
06/24/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/589,755	ITSCHAK, LAMENSDORF	
	Examiner	Art Unit	
	Jane Zara	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-82* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-82* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-58 drawn to nucleic acid compositions.

Group II, claim(s) 59, drawn to a method of synthesis of a molecule.

Group III, claim(s) 60-68, drawn to a method of delivering a nucleic acid sequence to a cell.

Group IV, claim(s) 69-72, drawn to a method for intracellular targeting of a nucleic acid sequence.

Group V, claim(s) 73-76, drawn to a method of delivering a nucleic acid sequence to the brain.

Group VI, claim(s) 77, drawn to a method of delivering a nucleic acid sequence to the spinal cord.

Group VII, claim(s) 78-80, drawn to a method of modulating iNOS gene expression.

Group VIII, claim(s) 73-76, drawn to methods of treating, controlling or preventing a disease.

This application contains claims directed to a plurality of patentably distinct nucleic acid molecules. The myriad of molecules represented by the formulas claimed, including formulas I-VIII in claims 1 and 23, and the many possible combinations that are represented by L, N, H, P, i, r, q, s, t, x, and the various R groups, encompass countless numbers of structurally and functionally distinct oligomeric compounds. The

compounds are independent or distinct because the different oligomeric compounds, defined by the various formulas recited in the claims, have different structures and, therefore, different chemical properties and biological effects. For example, the different oligomers or nucleic acids may differ with regard to solubility, cellular uptake, and nuclease stability, all of which are expected to contribute to their mode of action in vivo and in vitro. The different molecules would also differ in their reactivity and the starting materials from which they are made. It is also possible that the method and utility of each molecule would differ according to the best mode of administration or delivery required for each one and the particular applications each is suited for.

Similar reasoning applies to the compounds recited in Groups I - VIII claims 1-82, which recite a plurality of distinct oligomeric compounds, having distinct sugar-nucleobase-internucleoside, amino acid and peptide chemistries, and which encompass hundreds, if not thousands, of possible substituents recited in claims 1-82.

Accordingly, Applicant is required to elect a **single** formula, and single type of nucleic acid molecule, and a **single** peptide ligand, hydrophobic moiety, peptide protecting group, positively charged moiety, and linker moiety with the elected Group from claims 1-82 (see, e.g., claims 1, 2, 3, 4, 6, 7, 8, 10, 13, 14, 16, 17, 18…).

The inventions listed as Groups I-VIII, and the various nucleic acid molecules, linkers, positively charged moieties, peptide moieties, etc. do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Claims 1-82 are drawn to compositions, methods, and processes comprising or utilizing a myriad of different nucleic acid molecules. Therefore, this application does not comply with the requirements for unity of invention (Rules 13.1, 13.2 and 13.3) for the following reasons:

According to the guidelines in section (f)(i)(a) of annex B of the PCT Administrative Instruction, the special technical feature as defined by PCT Rule 13.2 shall be considered to be met when all the alternatives of a Markush group are of similar nature. The instant methods, cells and compositions comprising or utilizing any of thousands of different molecules set forth in and/or encompassed by claims 1-82 are considered to be each separate inventions for the following reasons:

The different sequences, nucleic acids, targets, structures, processes, and methods do not meet the criteria of (A), common property or activity or (B)(2), art recognized class of compounds. In the instant case, the different target molecules, target genes, nucleic acids, formulae, peptide ligands, hydrophobic moieties, peptide protecting groups, positively charged moieties, and linker moieties are structurally and chemically and biologically different and distinct, and the different molecules and biological structures and entities, and the different methods and utilize distinct molecules for processes and to target different molecules, inhibit or modulate the expression of the target gene to varying degrees, or measure different phenotypes, biochemical and/or biological effects. Each member of the class cannot be substituted one for the other with the expectation that the same intended result would be achieved or measured.

Further, the different Groups of compounds and target molecules and processing constructs, and the different methods do not meet the criteria of (B)(1) as they do not share, one with another, a common core structure. Accordingly, unity of invention between the different structures claimed and their methods of use is lacking and each molecule is considered to constitute a special technical feature.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Conclusion

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices

published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. ' 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jane Zara whose telephone number is (571) 272-0765. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz, can be reached on (571) 272-0763. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jane Zara
6-19-09

/Jane Zara/
Primary Examiner, Art Unit 1635